

ALLEGED SHIPMENT: On or about February 6, 1948, by W. H. Reed & Co., Inc., from Atlanta, Ga.

PRODUCT: 43 dozen *phrophylactics* made from animal membrane at Kansas City, Mo. Examination of the articles showed that 8.3 percent were defective in that they contained holes.

LABEL, IN PART: "Black and Gold Manufactured by Olympia Laboratories."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "For the prevention of contagious diseases" was false and misleading as applied to an article containing holes.

DISPOSITION: May 26, 1948. W. H. Reed & Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for segregation and destruction of the unfit portion, under the supervision of the Federal Security Agency. After the segregation operations were begun, it was determined by the claimant that further work was not justified. In accordance with the claimant's desire, the entire lot was destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2473. Misbranding of Dr. Peter's Kuriko. U. S. v. 6 Dozen Bottles, etc. Tried to the jury. Decree of condemnation and destruction. Affirmed on appeal. (F. D. C. No. 11219. Sample No. 55919-F.)

LIBEL FILED: December 10, 1943, Western District of Washington; transferred to Eastern District of Wisconsin on April 18, 1944.

ALLEGED SHIPMENT: On or about October 26, 1943, by Dr. Peter Fahrney & Sons Co., from Chicago, Ill.

PRODUCT: 6 dozen bottles of *Dr. Peter's Kuriko* and a number of circulars entitled "Dr. Peter's Kuriko" at Poulsbo, Wash. Examination showed that the product consisted of a sweetened solution in water and alcohol of extracts of plant drugs, including a laxative drug such as senna.

LABEL, IN PART: "Alcohol 14 per cent Prepared from the following ingredients: Senna, Fennel, Mandrake Root, Peppermint, Spearmint, Mountain Mint, Horse-mint, Sarsaparilla, Sassafras, Hyssop, Blessed Thistle, Dittany, Ground Ivy, Johnswort, Lemon Balm, Sage, Spikenard, Yarrow."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and pictures on the bottle label and in the circular entitled "Dr. Peter's Kuriko" were false and misleading. It was charged that these statements and pictures represented and suggested that the article would be effective in the cure, mitigation, or treatment of functional constipation, nervousness, indigestion, upset stomach, headaches, loss of sleep and appetite, foul breath, coated tongue, general feeling of ill health, general malaise, and common colds, and that the product when taken as directed would not fulfill the promises of benefit stated and implied.

DISPOSITION: The case having been transferred to the Eastern District of Wisconsin for trial, Dr. Peter Fahrney & Sons Co., claimant, filed a motion to transfer the case to the Northern District of Illinois. The motion was argued on May 31, 1944, and the court handed down the following opinion denying the claimant's motion:

F. RYAN DUFFY, *District Judge*: "The claimant, an Illinois corporation, with its principal place of business at Chicago, moves for an order transferring this proceeding to the United States District Court for the Northern District of Illinois, Eastern Division, asserting that trial in this district would cause it undue hardship, prevent it from making proper proof of its defenses, and cause great inconvenience to its witnesses, even preventing some of them, whose testimony would be material, from attending the trial."

*See also Nos. 2452-2455, 2458, 2459, 2461, 2465, 2466, 2468, 2470-2472.

"This proceeding is under the Federal Food, Drug and Cosmetic Act (52 Stat. Sec. 1040, 21 U. S. C. A., Sec. 301 et seq.), and was commenced on December 10, 1943, in the United States District Court for the Western District of Washington, Northern Division. Claimant was allowed to intervene by that court, and on April 18, 1944, on claimant's motion, an order was entered transferring the proceeding to this court 'for trial,' the district thereof being 'a District of reasonable proximity to the intervenor's (claimant's) principal place of business.' As claimant had moved the district court in Washington that transfer be ordered 'to the United States District Court for the Northern District of Illinois, Eastern Division, or to a United States District Court within reasonable proximity of Chicago, Illinois, the principal place of business of said intervenor,' its present motion constitutes a second attempt to secure transfer to the district court in Illinois.

"In connection with the right to removals and the exercise thereof, Sec. 334 (a) of the act provides:

... the proceeding pending or instituted shall, on application of the claimant seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

"Manifestly, claimant's application for removal to the district court in Illinois was not granted by the district court in Washington, because the same would not have been and is not authorized. In the absence of stipulation between the parties the power of removal of the court of original jurisdiction is limited and restricted. Such court is required to order removal to 'a district of reasonable proximity to the claimant's principal place of business.' Accordingly, it would have been beyond the power of the district court in Washington to have removed this proceeding to the designated district court in Illinois.

"The power of removal is exclusively conferred under the act upon the court of original jurisdiction, barring, of course, the existence of a stipulation of the parties on the subject. As the latter element does not obtain in the instant situation, this court has no power to grant the requested removal. In other words, the right to removal is completely exhausted and no longer exists in this proceeding.

"Claimant contends, however, that this court may order the requested removal under Sec. 334 (f) (2) of the act, which provides:

The court to which such case was removed shall have the powers and be subject to the duties, for the purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

"As pointed out, the proceeding was removed, pursuant to the statute, to this court 'for trial' and not for any other purpose. The language of the act last quoted is consistent with such limitation and expressly negatives any power in this court to grant further removal on application. A claimant in proceedings of this nature is limited to a single application for removal which must be made to the court of original jurisdiction. My conclusions have complete support in the legislative history of the controlling statutory provisions.

"An order denying claimant's motion will be entered."

On June 7, 8, 11, and 12, 1945, the case was tried to a jury, which returned a special verdict in favor of the Government. The claimant thereupon filed a motion for judgment in its favor, notwithstanding the verdict and also moved for a new trial in the event of denial of the former. The claimant's motions were denied. The Government having moved for judgment on January 22, 1946, the court granted such motion and ordered the product condemned and destroyed.

The claimant having appealed on January 2, 1947, the Circuit Court of Appeals for the 7th Circuit handed down the following opinion, affirming the district court:

MAJOR, *Circuit Judge*: "This is an appeal from a decree entered January 22, 1946, in a proceeding commenced by the filing of a Libel Information under the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. 301 et seq., which prayed the condemnation of an article called Dr. Peter's Kuriko, on the ground

that it was misbranded when in interstate commerce. The *res* involved is a medicine manufactured by Dr. Peter Fahrney & Sons Company, referred to as the claimant which intervened and defended the action. The cause was tried to a jury and a special verdict was returned which constitutes the basis for the decree in controversy.

"The libel as filed charged misbranding in a number of ways, all of which charges have been eliminated in one way or another except that contained in paragraph IIIa, which alleged that the article was misbranded within the meaning of 21 U. S. C. A. 352 (a) in that certain representations in the labeling were false and misleading since the product, when taken as directed, will not fulfill the promises of benefit stated and implied therein.

"The special verdict of the jury, on questions framed by the court, was as follows:

1. Is the labeling of Kuriko false or misleading in that the product, when taken as directed, will not fulfill the promises of benefit, stated or implied?

Answer: Yes.

2. Does the labeling of Kuriko, including the directions thereon, provide for the continuous use of Kuriko?

Answer: No.

3. If you answer Question 2 "Yes," then answer this question. Is the continuous use of Kuriko capable of causing a dependency upon laxatives to move the bowels?

Answer:

4. Is Kuriko misbranded in that the labeling fails to bear adequate directions for use in any respect?

Answer: Yes.

"The primary issue raised before this court arises from the contention that there was no substantial evidence which would justify the submission of the case to the jury and that there should have been a directed verdict in favor of the claimant. It is also contended that the submission to the jury of question 4 was prejudicial error because there was no charge in the libel to which it was responsive. In connection with this contention, it is also asserted that the court improperly admitted the opinion testimony of a witness who was not qualified.

"Kuriko is a medicine which has long been manufactured and sold to the public. Admittedly, it is a laxative and relieves functional constipation. That is the limit, however, of its remedial qualities. In fact, we do not understand that anything further is claimed for it. Notwithstanding this, claimant in a pamphlet wrapped around each bottle of its product devoted four pages extolling benefits to be derived from its use. We think no good purpose could be served in setting forth the contents of this pamphlet. It is sufficient to state that we have studied it and we are of the view that the representations contained therein were such as to present a proper question for the jury as to whether they were misleading. It may be, as claimant insists, that there were no statements contained in the pamphlet which were literally false, but even so it does not follow that it was not misleading when considered in its entirety.

"We shall mention only a few of the statements contained in this pamphlet, from which we think a jury might have reasonably inferred that the product was represented either as a remedy or a cure for something other than constipation. On the first page, under the heading in large black type, 'What it is,' appears the following in small type, 'The family medicine of 5 generations designed for relief from functional constipation and, when these troubles are due to constipation, for relief from nervousness, indigestion, upset stomach, headaches, loss of sleep and appetite, flatulence, foul breath and coated tongue.' In other words, by this statement the reader is informed that the remedy is only a relief from the ailments mentioned when they are due to constipation. It appears there could be nothing misleading in this statement. On the same page, however, under another heading in large black type, 'What it does,' is the following statement, also in heavy type, 'Kuriko fights functional constipation.' The government contends that the buying public may infer from this statement that it is a remedy or cure for constipation rather than a mere relief. We are not greatly impressed with the government's contention in this respect but this representation, as others, was submitted to the jury and we cannot say that the jury was not justified in inferring that the statement was misleading.

"In our judgment, the more important statements in the pamphlet calculated to mislead are found on the second page, printed in large black type, 'Here's what may happen when you are constipated,' followed by five paragraphs,

entitled 'Functional constipation,' 'Nervousness,' 'Flatulence,' 'Headaches,' and 'Common colds.' The title of each paragraph is also in heavy black type, and opposite each is a picture of a person shown to be in misery and distress. It is true that the fine print in each of these paragraphs gives the information that Kuriko will bring relief only when the ailment is caused by constipation. We are of the view, however, that this page of the pamphlet alone, considering the form of its arrangement, the ailments which are listed in large type and the limitation with reference thereto in small type, in connection with the pictures of persons evidently in misery and distress, furnishes the basis for a finding that the representations were misleading.

"A great deal of medical testimony was offered by both sides which it is argued supports the contentions of the respective parties. Again we think no useful purpose could be served in an attempt to analyze or dissect this expert testimony as it pertains to the issues in controversy. In fact, to do so would involve a weighing of the testimony, which is not our function but was that of the jury. The only contention made here which might be regarded as serious is that which arises from the submission to the jury of question 4, and its finding that Kuriko is misbranded because the labeling 'fails to bear adequate directions for use in any respect.' Concededly there was no charge in the information to which this question and answer was responsive. The only reason we find for its submission is a statement by the court that it desired an answer to the question for its own information. We are of the view that this question should not have been submitted but, even so, we are also of the view that it was not prejudicial. As this court has held, proof of any one of the claims contained in the information is sufficient. *United States v. Dr. Roberts Veterinary Co.*, 104 F. 2d 785, 789.

"The jury's answer to this question neither adds nor detracts from its answer to the first question, which was responsive to the charge contained in paragraph IIIa. The answer to question 1 forms the basis for a decree and this irrespective of the answer to question 4. This would still be the situation if the jury's answer to question 4 had been 'No.' There is nothing to indicate and no reason to think that the jury's answer to question 4 bore any relation to its answer to question 1. In other words, as far as we are able to discern, the jury's answer to question 1 was not dependent in any manner or to any extent upon its answer to question 4. We therefore are of the view that the submission of question 4 could have had no prejudicial effect.

"The decree is **AFFIRMED.**"

2474. Misbranding of AlKaPectin. U. S. v. Reserve Research Co. and Herbert Williams Hoyt. Pleas of nolo contendere. Fine of \$125 and costs against defendants jointly. (F. D. C. No. 24276. Sample No. 16222-K.)

INFORMATION FILED: August 13, 1948, Northern District of Ohio, against the Reserve Research Co., a corporation, Cleveland, Ohio, and Herbert Williams Hoyt, president of the corporation.

ALLEGED SHIPMENT: On or about October 30, 1947, from the State of Ohio into the State of Michigan.

PRODUCT: Analysis disclosed that the product was a white, viscous, homogenized semisolid with a slight aromatic odor and contained chiefly water, kaolin and other aluminum compounds, and a small amount of organic matter.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Indicated in the treatment of Diarrhoea, Duodenitis, Colitis, Diverticulitis, Food Poisoning" was false and misleading, since the article would not be effective in the treatment of diarrhoea, duodenitis, colitis, diverticulitis, and food poisoning.

DISPOSITION: October 7, 1948. Pleas of nolo contendere having been entered, the court imposed a fine of \$125 and costs against the defendants jointly.

2475. Misbranding of Vitawine. U. S. v. Interstate Laboratories, Inc. Plea of guilty. Fine of \$258 and costs. (F. D. C. No. 24043. Sample Nos. 52696-H, 54133-H, 54135-H.)

INFORMATION FILED: March 10, 1948, Western District of Kentucky, against Interstate Laboratories, Inc., Louisville, Ky.

ALLEGED SHIPMENT: Between the approximate dates of September 9, 1946, and January 17, 1947, from the State of Kentucky into the State of Indiana.